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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/877,832      | 06/07/2001  | Jean-Damien Charrier | VPI/00-117          | 9982             |

27916 7590 05/10/2006

VERTEX PHARMACEUTICALS INC.  
130 WAVERLY STREET  
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| EXAMINER |
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BALASUBRAMANIAN, VENKATARAMAN

| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|---|--|--|--|
| <b>Advisory Action</b><br><b>Before the Filing of an Appeal Brief</b> | <b>Application No.</b><br>09/877,832               | <b>Applicant(s)</b><br>CHARRIER ET AL. |  |
|   | <b>Examiner</b><br>Venkataraman<br>Balasubramanian | <b>Art Unit</b><br>1624                |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 25 April 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 25 April 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attached Advisory Action. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: \_\_\_\_\_.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

*Venkataraman Balasubramanian*  
 Venkataraman Balasubramanian  
 Primary Examiner  
 Art Unit: 1624 5/5/06

### **ADVISORY ACTION**

The applicants' response, which included amendment to claim 9, filed 4/25/2006 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered for the following reasons.

Applicants should note that as indicated in the previous office action, if entered, claims 1-6, 9, 11 and 12 would be allowable.

However, the following 112 first paragraph rejection of claim 9 made in the previous office action would remain. To repeat:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

'Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preserving cells or organs or treating arthritis with the instant compound, does not reasonably provide enablement for various diseases embraced in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is same as made in the previous office action and these claims remain rejected for reasons of record.

Applicants' argument presented in the previous response to overcome this rejection with volume of references, which merely show desirability of inhibiting caspase

activity to regulate inflammation, does not obviate this rejection, as they have not shown direct nexus between each disease claimed in long list of diseases and classes of disease and caspase activity recited in these claims.

Furthermore, reading some of these references particularly the conclusion section appears to imply that these studies are still at experimental stage, needs further studies. Based on these it appears that substantiation of utility and its scope requirement when utility is "speculative", "sufficiently unusual" or not provided, is still not met with. See *Ex parte Jovanovics*, 211 USPQ 907, 909; *In re Langer* 183 USPQ 288. Also note *Hoffman v. Klaus* 9 USPQ 2d 1657 and *Ex parte Powers* 220 USPQ 925 regarding type of testing needed to support in vivo uses.

In addition, some of the references cited extend well beyond the date of filing of instant application and it is not possible to select which are prior art and which are not as presented.

Finally, applicants should note that this rejection is scope of enablement rejection and hence all diseases embraced in these claims so generically need to be analyzed for enablement requirement.

This rejection is same as made in the previous office action. Applicants' have not addressed the issues or provide evidence that a single class of compound based on the mode of action is useful for treating any or all diseases as embraced in the instant method claims.

Hence this rejection is proper and is maintained'.

**Response to Applicants' traversal:**

This rejection is same as made in the previous office action and is still applicable to the claim 9.

As for applicants' present amendment (dated 4/25/2006) of claim 9, although applicants' have limited the diseases to specific diseases as compare generic diseases by instant amendment, there is no enabling disclosure for these various diseases. Prior art search made earlier did not suggest scope of enablement for all the diseases embraced in the instant claim 9.

Hence, this rejection is proper and is maintained.

**Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For

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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

*Venkataraman Balasubramanian*  
Venkataraman Balasubramanian

5/5/2006